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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,860	07/12/2004	Jeffrey Owen Phillips	04242373	1266

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

NOTIFICATION DATE	DELIVERY MODE
08/21/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No.	Applicant(s)	
	10/795,860	PHILLIPS, JEFFREY OWEN	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75 and 77-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75 and 77-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20081003;20080521,20080417*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

This application repeats a substantial portion of prior Application No. 10/407,552, filed 4/4/2003, and adds and claims additional disclosure not presented in the prior application (See below). Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Specification

The amendment filed 6/11/2007 with respect to the Specification is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The range of "about 0.75 mEq (mmole) to about mEq(mmol) per 2 mg of omeprazole". The remarks do not indicate how the range was determined and what specific disclosure in the original specification and/or claims support the amendment.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Examiner has reviewed the IFW file and Preliminary Amendment D amends the claims. It does not appear to provide support for amendment to the Specification of the above. .

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 75, 77-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 75, 77-92 contains the limitation “about 56 to about 97 wt-%”. There is no support for this limitation as the disclosure cited by the Applicant does not set forth the same.

The Examine has duly considered the Applicant’s arguments but deems them unpersuasive.

No where in the example cited is the term "about " set forth. Since "about" includes amounts falling outside the derived range, said term is not supported by the derived range.

Claims 77-91 contains the limitation “about 1 to about 4 wt-%”. There is no support for this limitation as the disclosure cited by the Applicant does not set forth the same.

The Examiner has duly considered the Applicant’s arguments but deems them unpersuasive.

No where in the example cited is the term "about " set forth. Since "about" includes amounts falling outside the derived range, said term is not supported by the derived range. Further, the lowest calculated value is 1.3 wt% and the highest calculated valued is 3.8 wt.%. As such, the derived range cannot have low end of 1% or a high end of 4%.

Claim 83 contains the limitation "about 250 to about 500 mg". There is no support for this limitation as the disclosure cited by the Applicant does not set forth a range or an approximate amount.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

No where in the example cited is the term "about " set forth. Since "about" includes amounts falling outside the derived range, said term is not supported by the derived range.

Claim 88 contains the limitation "about 7 mEq to about 25 mEq". There is no support for this limitation in that the disclosure cited indicates that the range is "per 20 mg of omeprazole" and the Applicant has not shown that the range works within the requirements of claim 75 as to the amount of the PPI and amount of buffer.

The Applicant does not appear to have addressed this rejection.

Claim 90 was amended so that instead of "per mg" it now reads as "about 0.1 mEq to about 5 mEq per 2 mg of proton pump inhibitor".

The Applicant does not appear to indicate how this overcame the rejection to claim 90. As indicated in the prior Office Action, the Applicant's citation to the Specification did not support this limitation. The Specification at page 32, lines 1-5, indicates a range of approximately 0.2 mEq to 5 mEq of sodium bicarbonate per 2 mg of omeprazole in a solution. If the Applicant's arguments were valid with respect to the differences between solutions and solid formulations than one of ordinary skill in the art would not be able to extrapolate to a solid dosage form. Even if the Applicant's arguments were not valid, there is no showing that mEqs of sodium bicarbonate suitable for 2 mg omeprazole would be suitable for PPI's in general.

Claim 91 contains the limitation "about 1 mEq to about 25 mEq". There is no support for this limitation as the disclosure cited by the Applicant does not set forth this range and the minimum of 1 mEq was disclosed in relation to 1 mEq per 2mg omeprazole.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant cites to page 93, lines 25-27 as support for the limitation. There is no page 93 in the Specification as the last page of the Specification is page 90 which does not appear to provide any support for said limitation.

Claim 92 contains the limitation "absorbed within about 10 to about 60 minutes". There is no support for this limitation in that the disclosure cited by Applicant refers to a solution not a tablet.

The Applicant does not appear to have addressed this rejection.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

With respect to the rejections below, since the Applicant has filed preliminary amendments containing new matter with respect to the Specification and claims, the Applicant is only entitled to the filing date of the present Application of March 8, 2004.

Claims 75, 77-86, 88-92 are rejected under 35 U.S.C. 102(b) as being rejected by Phillip (US Pat. 6,489,346).

Phillip expressly discloses tablets as follows:

B. 10 mg Tablet Formula

Omeprazole	10 mg (or lansoprazole or pantoprazole or other PPI in an equipotent amount)
Calcium lactate	175 mg
Calcium glycerophosphate	175 mg
Sodium bicarbonate	250 mg
Aspartame calcium (phenylalanine)	0.5 mg
Colloidal silicon dioxide	12 mg
Corn starch	15 mg
Croscarmellose sodium	12 mg
Dextrose	10 mg
Peppermint	3 mg
Maltodextrin	3 mg
Mannitol	3 mg
Pregelatinized starch	3 mg

C. 20 mg Tablet Formula

Omeprazole	20 mg (or lansoprazole or pantoprazole or other PPI in an equipotent amount)
Calcium lactate	175 mg
Calcium glycerophosphate	175 mg
Sodium bicarbonate	250 mg
Aspartame calcium (phenylalanine)	0.5 mg
Colloidal silicon dioxide	12 mg
Corn starch	15 mg
Croscarmellose sodium	12 mg
Dextrose	10 mg
Peppermint	3 mg
Maltodextrin	3 mg
Mannitol	3 mg
Pregelatinized starch	3 mg

D. Tablet for Rapid Dissolution

Omeprazole	20 mg (or lansoprazole or pantoprazole or other PPI in an equipotent amount)
Calcium lactate	175 mg
Calcium glycerophosphate	175 mg
Sodium bicarbonate	500 mg
Calcium hydroxide	80 mg
Croscarmellose sodium	12 mg

Claims 75, 77-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 584,588 in view Carroll or McCullough (US Pat. 5,447,918) each in view of Kim et al. (US Pat. 5,703,097), Whittle et al. (US Pat. 6,268,385) and the acknowledged prior art.

EP 584,588 discloses a non-enteric coated anti-ulcer PPI and a basic material, such as alumina magnesium hydroxide, aluminum hydroxide, magnesium hydroxide, sodium carbonate, calcium carbonate, magnesium carbonate, sodium hydrogen carbonate, potassium hydrogen carbonate, magnesium hydrogen carbonate, calcium hydrogen carbonate, and that the amount of basic material may be present in an amount of 50 to 2000 weights per 100 weight parts (Pages 3-6). It is disclosed that the basic material is used to preserve the stability of the acid-labile imidazole derivative in the stomach (Page 6, lines 19-21). It is disclosed that omeprazole and imidazole derivative are both acid-labile (Example 1 at pages 6,7). It is disclosed that the composition can be administered orally, in the form of tablets, pellets, capsules, powder, granules, syrup, paste and the like and that they can contain excipients, disintegrants, binders, lubricants, pigments, diluents and the like which are commonly employed in the art (Page, 6, lines 28-35).

Carroll et al. disclose the use of sodium bicarbonate to stabilize omeprazole in the gastric environment (Abstract).

McCullough disclose a tablet containing 20-300 mg omeprazole, 400-500 mg calcium carbonate, sucralfate, simethicone, sodium saccharin, corn starch, carboxymethyl cellulose, magnesium stearate and flavor (Columns 15, 16, example 12). The use of one or more of aluminum hydroxide, magnesium hydroxide, potassium or sodium bicarbonate, calcium carbonate, magnesium carbonate is also disclosed (Column 8, lines 15-35).

Kim et al. discloses a method of treatment of treatment of gastric and duodenal ulcers and reducing acidity with 5-pyrrolyl-2-pyridylmethylsulfinylbenzimidazole derivatives which are dosed generally at 1 to 1000 mg/day, preferably 3 3to 100 mg/day and also discloses

comparative tests with omeprazole in the reduction of acidity (column 11, lines 20-31, Column 16, lines 45-68, Columns 17-20).

Whittle et al. discloses that esomeprazole is S-omeprazole (Column 19, lines 51-54). Methods of preparing oral dosage forms including mixing the active ingredient with an alkali material which creates a micro-pH of not less than pH of 7, preferably not less than a pH of 8 chosen from such materials as sodium, potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, or other suitable weak inorganic or organic acids; substances typically used in antacid preparations such as aluminum, calcium, and magnesium hydroxides; magnesium oxide or composite substances such as, for example, Al.sub.2 O.sub.3.6MgO CO.sub.2.12H.sub.2 O (Mg.sub.6 Al.sub.2.(OH).sub.16 CO.sub.3 4H.sub.2 O), MgO.Al.sub.2 O.sub.3, 2SiO.sub.2.nH.sub.2 O, wherein n is not necessarily a whole number and may be less than 2, or similar compounds (Column 43, lines 6-34). It is disclosed that the above mixture may then be formulated into pellets or tablets or gelatin capsules which may then be used as cores for further processing, for example, enteric coating (column 43, column 44). It is disclosed that the tablets can contain lubricating agents, fillers and bulking agents and disintegrating agents (Columns 41, 42). It is disclosed that the preferred dosages of the active ingredients is from about 8 mg to about 10 mg, about 16 mg to about 20 mg, and about 32 mg to about 40 mg, especially 10 mg, 20 mg and 40 mg per dosage unit (Column 41, lines 9-20).

The Applicant acknowledges that omeprazole and lanzoprazole are H+, K+-ATPase proton pump inhibitors (Specification, Page 12)

The prior art disclose the combination of PPI and basic material, such as sodium bicarbonate. The difference between the prior art and the claimed invention is that the prior art

does not expressly disclose 10-40 mg of non-enteric coated benzimdazole PPI in combination with about 56 wt% to about 97 wt% of a buffer comprising sodium bicarbonate and excipients containing disintegrant, lubricant and binder. However, the prior art amply suggests the same as the prior art discloses a non-enteric coated formulation containing basic material and omeprazole, that omeprazole is acid sensitive, the use of buffering agents such as sodium bicarbonate and magnesium hydroxide and tablets containing excipients such as disintegrants, lubricants, fillers and bulking agents. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation the combination of the non-enteric coated PPI with the basic substance, such as sodium bicarbonate and magnesium hydroxide, would protect the PPI from stomach acid and that the product can be effectively administered as a tablet.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

Contrary to the Applicant's arguments, the Examiner has provided the reasoning for combining the prior art as indicated above. Nomura does not teach away from the claimed invention. The PPI ratio is in relation to the imidazole derivative and omeprazole is not used as a negative control but simply to show that the imidazole derivative is also acid labile similar to omeprazole. The passage of Nomura cited stated does not state that omeprazole and lansoparaozle must be enteric coated only that the currently available omepraozle and lanzoprazole preparations use enteric coating as a method of protecting the same against stomach acid.

The fact that Carroll describes a liquid preparation is not sufficient to overcome the rejection. According to the Specification, the claimed solid compounds can be first mixed with a liquid prior to administration. Further, the Applicant uses a liquid formulation as support for its absorption time. In any case, the rejection herein is based on a combination of references, as such, there is no requirement that Carroll disclose a solid formulation. The prior art does disclose the formulation of both solid and liquid preparations as indicated above. The fact that drug formulations can have different absorption rates and times based on formulation and route of administration is not sufficient to overcome the rejection. Given that the prior art discloses both the preparation of liquid and solid oral dosages, the Applicant has not provided evidence that it is outside the skill of one of ordinary skill in the art to adjust dosage and excipients based on desired absorption rates.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 75, 77-92 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 162-196 of copending Application No. 10/407,552. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass tablets containing the combination non-enteric coated benzimadazole PPI, sodium bicarbonate and other buffers, including magnesium hydroxide, and binder, disintegrant and lubricant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 75, 77-92 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-29 of U.S. Patent No. 6,7890,882. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass tablets containing the combination non-enteric coated benzimadazole PPI, sodium bicarbonate and other buffers, including magnesium hydroxide, and binder, disintegrant and lubricant.

With respect to the above, the Applicant has not traversed the same, as such, the double patenting rejections are maintained.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
August 19, 2009

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617